

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships in Language and Communication.

Date: July 6, 2009.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Chicago, 151 East Wacker Drive, Chicago, IL 60601.

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892. 301-435-2309. pluded@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 22, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-15584 Filed 6-30-09; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Pain Control by Selective Ablation of Pain-Sensing Neurons by Administration of Resiniferatoxin

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in PCT Patent Application PCT/US2001/09425 [HHS Ref. E-109-2000/0-PCT-01], US Patent Application 10/472,874 [HHS Ref. E-109-2000/0-US-02], both entitled "Molecular Neurochirurgie for Pain Control Administering Locally Capsaicin or Resiniferatoxin", and Canadian Patent Application 2442049 [HHS Ref. E-109-2000/0-CA-03] entitled "Selective Ablation of Pain-Sensing Neurons by Administration of a Vanilloid Receptor Agonist", and all continuing applications and foreign counterparts, to Sherrington Pharmaceuticals, which has offices in New York, N.Y. The patent rights in these inventions have been assigned to

and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

All fields of use, both human and veterinary, covered under the above listed patents, for the life of these patents; the selective ablation of pain-sensing neurons using vanilloid receptor agonists including resiniferatoxin and capsaicin using localized delivery, including intrathecal and intraganglionic injection.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 31, 2009 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Norbert Pontzer, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; *Telephone:* (301) 435-5502; *Facsimile:* (301) 402-0220; *E-mail:* pontzern@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Pain pathways, including those mediating severe pain associated with chronic and terminal diseases, have unique receptors (termed vanilloid or more recently TRPV1) that mediate the transmission of nociceptive sensory signals from the periphery through the spinal cord to the brain. Compounds such as capsaicin from hot peppers activate pain neurons by opening cation channels linked to TRPV1 receptors on nerve terminals and cell bodies. NIH inventors discovered that resiniferatoxin (RTX) is an extremely potent TRPV1 receptor agonist that produces a calcium overload and selectively degeneration of pain neurons when cell body TRPV1 receptors are activated by RTX. Intrathecal or intraganglionic administration of RTX can thus cause the permanent and selective destruction of the pain neurons in the CNS displaying TRPV1 receptors. This invention allows pain control in human and other animals with intractable pain through selective ablation of pain pathway neurons.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant

of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 19, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9-15576 Filed 6-30-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0294]

Regulation of Tobacco Products; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain information on the implementation of the Family Smoking Prevention and Tobacco Control Act. FDA is establishing this docket in order to provide an opportunity for all interested parties to provide information and share views on the implementation of the new law.

DATES: Submit written or electronic comments by September 29, 2009.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., WO1, rm. 4300, Silver Spring, MD 20993, 301-796-4830, FAX: 301-847-3541, Erik.Mettler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Tobacco products are responsible for more than 430,000 deaths each year. The Centers for Disease Control and Prevention (CDC) report an estimated 60

million adults smoke cigarettes in the United States, even though this behavior will result in death or disability for half of all regular users. Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total \$193 billion annually in medical expenditures and lost productivity. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time.

On June 22, 2009, the President signed H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, into law. The Family Smoking Prevention and Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Family Smoking Prevention and Tobacco Control Act authorizes FDA to require disclosure of tobacco product ingredients and additives; regulate "modified risk" tobacco products; create standards for tobacco products, including standards for the reduction or elimination of certain constituents; restrict sales, distribution, advertising, and promotion of tobacco products; and require stronger health warnings on packaging. The Family Smoking Prevention and Tobacco Control Act also requires FDA to issue its 1996 final regulation restricting the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products. The rule contains provisions designed to limit young people's access to tobacco products, as well as restrictions on marketing to curb the appeal of these products to minors.

We are requesting comments that will inform strategies to protect the public health as we implement this new authority. A copy of the Family Smoking Prevention and Tobacco Control Act is available on the agency's Web site at <http://www.fda.gov/tobacco>.

II. Request for Comments and Information

We are particularly interested in comments on the approaches and actions the agency should consider initially to increase the likelihood of reducing the incidence and prevalence of tobacco product use and protecting the public health. Although the agency will not respond to specific suggestions, we will consider them in establishing the new Center for Tobacco Products and in implementing the Family Smoking Prevention and Tobacco Control Act. In the future, we intend to solicit public input on specific issues. Please organize any comments you have

in response to this notice using these general categories:

- Federal, State, and local government collaboration;
- New product submission and approval;
- Product ingredient disclosure;
- Prevention;
- Tobacco use by specific groups including minors, women, and racial and ethnic minority populations;
- Tobacco addiction;
- Smoking cessation;
- Data collection;
- Products with "reduced harm/risk" claims;
- Enforcement;
- Research and testing;
- Advertising and marketing of tobacco products;
- Label statements and warnings (including graphic warnings);
- Tobacco product standards (including flavors, ingredients, etc.);
- Sale and distribution of tobacco products;
- Manufacturing restrictions and facilities controls; and
- Other.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-15549 Filed 6-30-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2009-0035]

National Protection and Programs Directorate, Office of Infrastructure Protection; Submission for Chemical Facility Anti-Terrorism Standards Information Collection 1670-NEW.

AGENCY: National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Security Compliance Division, DHS.

ACTION: 60-Day Notice and request for comments: New information collection request 1670-NEW.

SUMMARY: The Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Security Compliance Division (ISCD) will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is a new information collection. The purpose of this notice is to solicit comments during a 60-day public comment period prior to the submission of this collection to OMB. The submission describes the nature of the information collection, the categories of respondents, the estimated burden and cost.

DATES: Comments are encouraged and will be accepted until August 31, 2009. This process is conducted in accordance with 5 CFR 1320.8.

ADDRESSES: Interested persons are invited to submit comments on the proposed information collection through Federal Rulemaking Portal at <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments must be identified by docket number DHS-2009-0035.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained through Federal Rulemaking Portal at <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

Program Description

The Chemical Facility Anti-Terrorism Standards (CFATS), 6 CFR Part 27, are the Department's regulations under Section 550 governing security at high-risk chemical facilities. CFATS represents a national-level effort to minimize terrorism risk to such facilities. Its design and implementation balance maintaining economic vitality with securing facilities and their surrounding communities. The regulations were designed, in collaboration with the private sector and other stakeholders, to take advantage of protective measures already in place and to allow facilities to employ a wide range of tailored measures to satisfy the regulations' Risk-Based Performance Standards (RBPS).

The instruments within this collection will be used to manage the CFATS program.